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Paper No. 55

STEPHEN S. SADACCA
LOCKHEED MARTIN CORPORATION
MAIL STOP WT-05
P.O. BOX650003
DALLAS TX 75265-0003

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JUN 2 8 2005

OFFICE OF PETITIONS

In re Application of
Monroe
Application No. 04/520,820
Filed: December 20, 1965
Attorney Docket No. 10919-16601
For: GUIDED MISSILE DEFENSE METHOD AND APPARATUS

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.137(b), filed March 3, 2005 (certificate of mailing date February 28, 2005), to revive the above-identified application.

This application became abandoned for failure to timely pay the issue fee within three (3) months of the mailing of the July 20, 2004 Notice of Allowance and Fee(s) Due. Accordingly, this application became abandoned on October 21, 2004. A Notice of Abandonment was mailed on January 13, 2005.

Applicant has submitted a proper reply in the form of the issue fee and a completed PTOL-85, an acceptable statement of the unintentional nature of the delay in responding to the July 20, 2004 Notice of Allowance and Fee(s) Due, a terminal disclaimer, and the petition fee.

The terminal disclaimed filed March 3, 2005 (certificate of mailing date February 28, 2005) under 37 CFR 1.137(c) has been entered and made of record. Effective September 8, 2000, 37 CFR 1.137(c)(1) has been added to state that a terminal disclaimer filed pursuant to this rule must dedicate to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: 1) the period of abandonment of the application; or 2) the period extending beyond twenty years from the date on which the application for the patent was filed in the United States, or, if the application contains a specific reference to an earlier filed application(s) under 35 U.S.C.

120, 121 or 365(c), from the date on which the earliest such application was filed. 65 Fed. Reg. 54,674 (2000). Accordingly, the period of the terminal disclaimer filed March 3, 2005 (certificate of mailing date February 28, 2005) will be equivalent to the lesser of period (1) or (2), as noted above, for this application.

The petition is **granted**.

This application is being forwarded to Publishing Division for processing into a patent.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3230.

E. Shirene Willis

E. Shirene Willis
Senior Petitions Attorney
Office of Petitions

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FROM DIRECTORS OFFICE Paper no. 32

JAN 05 2007

TECHNOLOGY CENTER 3600

RICHARD S. SCIASCIA
OFC. OF NAVAL RESEARCH (CODE 320)
DEPT. OF THE NAVY
ARLINGTON VA 22217

In re Application of	:	DECISION ON REQUEST
William H. Fiden	:	TO WITHDRAW
SERIAL NO.: 05/626,674	:	HOLDING OF
FILED: October 28, 1975	:	ABANDONMENT
FOR: RADAR-COMPATIBLE DATA LINK SYSTEM		

The application was abandoned for failure to timely respond to the Office action mailed September 6, 2002 which included a 2 month period for response.

Petitioner asserts that a response was in fact timely-filed and presents a copy of the response with a certificate of mailing dated September 23, 2002 and a statement under 37CFR 1.8 (b)(3) signed by the person who signed the original Certificate of Mailing.

The evidence is sufficient to show timely receipt of the response.

The request to withdraw the holding of abandonment is GRANTED.

The application is being forwarded to the examiner for action on the response.

Donald T. Hajec

Director, T.C. 3600
703-306-4180

tht: 02-17-05

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RAYTHEON COMPANY
C/O DALY, CROWLEY, MOFFORD & DURKEE, LLP
354A TURNPIKE STREET
SUITE 301A
CANTON MA 02021

MAILED

NOV 18 2009

OFFICE OF PETITIONS

In re Application of
George Spencer
Application No. 05/879,642
Filed: February 16, 1978

DECISION ON PETITION

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed March 29, 2001, resubmitted on August 1, 2005, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned for failure to timely pay the issue fee on or before December 14, 2000, as required by the Notice of Allowance and Fee(s) Due, mailed September 14, 2000. Accordingly, the date of abandonment of this application is December 15, 2000. The Notice of Abandonment was mailed February 15, 2001.

The petition satisfies the requirements of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of payment of the issue fee of $1,240, (2) the petition fee of $1,240; (3) a terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.27(d); and (4) a proper statement of unintentional delay.

37 CFR 1.137(b)(3) requires a statement that "the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional." Since the statement appearing in the petition varies from the language required by 37 CFR 1.137(b)(3), the statement is being construed as the required statement. Petitioner must notify the Office if this is not a correct reading of the statement appearing in the petition.

The application file does not indicate a change of address has been filed in this case, although the address given on the petition differs from the address of record. A change of address should be filed in this case in accordance with MPEP 601.03. A courtesy copy of this decision is being

mailed to the address noted on the petition. However, until otherwise instructed, all future correspondence regarding this application will be mailed solely to the address of record.

Telephone inquiries concerning this decision should be directed to Terri Johnson at (571) 272-2991.

This application is being referred to the Office of Data Management for processing into a patent.

Terri Johnson
Petitions Examiner
Office of Petitions

cc: **Donald F. Mofford**
Daly, Crowley & Mofford, LLP
275 Turnpike Street, Suite 101
Canton, MA 02021-2310

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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AFLSA/JACN-P
1501 WILSON BLVD. SUITE 805
ARLINGTON, VA 22209

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NOV 13 2006

OFFICE OF PETITIONS

In re Application of :
KIRTCHIK :
Application No. 05/924,404 : DECISION ON PETITION
Filed: July 11, 1978 : TO WITHDRAW
Attorney Docket No. 11889 : FROM RECORD
:

This is a decision on the Request to Withdraw as attorney or agent of record under 37 C.F.R. § 1.36(b), filed August 3, 2006.

The request is **NOT APPROVED**.

A grantable request to withdraw as attorney/agent of record must be signed by every attorney/agent seeking to withdraw or contain a clear indication that one attorney is signing on behalf of another/others. A request to withdraw will not be approved unless at least 30 (thirty) days would remain between the date of approval and the later of the expiration date of a time to file a response or the expiration date of the maximum time period which can be extended under 37 C.F.R. § 1.136(a).

The request cannot be approved because there is no clear indication as to whether attorney is signing on behalf of himself or all attorneys of record.

The Office cannot approve the request at this time since the reasons provided do not meet any of the conditions under the mandatory or permissive categories enumerated in 37 CFR 10.40. Section 10.40 of Title 37 of the Code of Federal Regulation states, "[a] practitioner shall not withdraw from employment in a proceeding before the Office without permission from the Office[.]" More specifically, 37 CFR 10.40 states, "[i]f paragraph (b) of this section is not applicable, a practitioner may not request permission to withdraw in matter pending before the Office unless such request or such withdrawal is" for one the permissive reasons listed in 37 CFR 10.40(c). The reasons set forth in the request, "the office function of the attorney is being transferred", does not meet any of the conditions set forth in 37 CFR 10.40.

All future communications from the Office will continue to be directed to the above-listed address until otherwise notified by applicant.

Telephone inquiries concerning this decision should be directed to the undersigned at 571-272-7253.

Monica A. Graves
Petitions Examiner
Office of Petitions

cc: **DEPARTMENT OF THE AIR FORCE**
AFMC LO/JAZ
2240 B ST., RM. 100
WRIGHT-PATTERSON AFB, OH 45433-7109

UNITED STATES PATENT AND TRADEMARK OFFICE

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WILLIAM AUTON
US Air Force
ESC/JAZ
40 Wright St Bldg 1120
Hanscom Afb, MA 01731

In re Application of :
KIRTCHIK :
Application No. 05/924,406 : DECISION ON PETITION
Filed: July 11, 1978 : TO WITHDRAW
Attorney Docket No. 11,890 : FROM RECORD
:

This is a decision on the Request to Withdraw as attorney or agent under 37 C.F.R. § 1.36(b) or 37 C.F.R. § 10.40 filed August 03, 2006.

The request is **NOT APPROVED**.

A review of the file record indicates that William G. Auton does not have power of attorney in this patent application nor is there any statement or evidence of record of employment in or otherwise being engaged in the proceedings in this patent application. Accordingly, the request to withdraw under 37 C.F.R. § 1.36(b) is not applicable.

All future communications from the Office will continue to be directed to the below-listed address until otherwise properly notified by the applicant.

Telephone inquires concerning this decision should be directed to Patricia Volpe at 571-272-6825.

Patricia Volpe
Petitions Examiner
Office of Petitions

cc: AFLSA/JACP
1501 WILSON BOULEVARD
ROOM 805
ARLINGTON, VA 22209

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

COPY MAILED

NOV 19 2008

OFFICE OF PETITIONS

In re Patent No. 4,272,953	:	
Issue Date: June 16, 1981	:	
Application No. 05/954,838	:	DECISION ON PETITION
Filed: October 26, 1978	:	
For: REHEAT GAS TURBINE COMBINED	:	
WITH STEAM TURBINE	:	

This is a decision on the petition filed September 4, 2008 entitled "PETITION FOR REPLACEMENT LETTERS PATENT UNDER 37 C.F.R. § 1.182", for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

As authorized, the $400 fee for the petition under 37 CFR 1.182 has been assessed to petitioner's credit card account.

Telephone inquiries concerning this decision may be directed to the undersigned at (571) 272-3208. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Niomi Farmer in the Office of Data Management at (703) 308-9250, Ext. 139.

A copy of this decision is being faxed to the Office of Data Management for issuance of a duplicate Letters Patent.

Karen Creasy
Petitions Examiner
Office of Petitions

cc: Niomi Farmer, South Tower, 8th Floor, Room C23 (Fax No. (571) 270-9753)

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

#27

William Squire
Carello, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein
6 Becker Farm Road
Roseland NJ 07068

Re: Patent Term Extension Application for U.S. Patent No. 4,291,708

Dear Mr. Squire:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,291,708 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: T-Scan 2000

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Yeda Research and Development Co.	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,291,708	:	INTERIM EXTENSION

Yeda Research and Development Co., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,291,708, filed an application for patent term extension under 35 U.S.C. § 156 on May 21, 1999. The term of the patent has been previously extended under 35 U.S.C. §§ 156(d)(5) and (e)(2) until November 2, 2000. The patent claims the medical device "T-Scan 2000" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on April 16, 1999. An extension of 1,826 days is requested.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by FDA. Since the extended term of the patent expired before a certificate of patent term extension could be issued, an additional interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,291,708 is granted for a period of one year from the extended expiration date of the patent, until November 2, 2001.

JAN 30 2001
Date

Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

JUL 9 2002

William Squire
Carella, Bryne, Bain, Gilfillan, Cecchi, Stewart & Olstein
6 Becker Farm Road
Roseland NJ 07068

Re: Patent Term Extension
Application for
U.S. Patent No. 4,291,708

Dear Mr. Squire:

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,291,708 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: T-Scan 2000®

FDA Docket No.: 98E-0851

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Yeda Research and Development	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,291,708	:	**INTERIM EXTENSION**

Yeda Research and Development, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,291,708, filed an application for patent term extension under 35 U.S.C. § 156 on May 21, 1999. An extension of five years is requested. The term of the patent has been previously extended under 35 U.S.C. §§ 156(d)(5) and (e)(2) until November 1, 2001. The patent claims the medical device "T-Scan 2000" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on April 16, 1999.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. On January 24, 2002 (67 Fed. Reg. 3501), FDA published the determination of the regulatory review period for purposes of patent term extension for "T-Scan 2000," but this determination has not yet been made final. Since the extended term of the patent expired before a certificate of patent term extension could be issued, an additional interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,291,708 is granted for a period of one year from the extended expiration date of the patent, i.e., until November 2, 2002.

JUL - 8 2002

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON TX 77056

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JUN 19 2008

OFFICE OF PETITIONS

In re Patent No. 4,314,442
Issue Date: February 9, 1982
Application No. 06/047,571
Filed: June 11, 1979
Attorney Docket No. CASE 1-A

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.182, filed May 20, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

The Office is in receipt of the $400 petition fee.

Telephone inquiries concerning this decision may be directed to the undersigned at (571) 272-3215. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Ms. Niomi Farmer, Office of Data Management, Phone: 703-308-9250 x129.

A copy of this decision is being faxed to Publishing Division for issuance of a duplicate Letters Patent.

Charlema Grant
Petitions Attorney
Office of Petitions

cc: Ms. Niomi Farmer, Office of Data Management, Fax: 571-270-9753.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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Dr. Diana Hamlet-Cox
Intellectual Property for Incyte Corporation
1360 Porter Drive
Palo Alto CA 94304

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MAR 16 2009

OFFICE OF PETITIONS

In re Application of :
Tang et al. :
Application No. 06/308184 : DECISION ON PETITION
Filing or 371(c) Date: 09/28/1981 :
Patent Number: 6958725 :
Issue Date: 10/25/2005 :
Title of Invention: :
RADOME ABERRATION CORRECTING SYSTEM :

This is a Decision in response to the Petition Under 37 C.F.R. § 1.59(b) to Expunge Information Unintentionally Submitted in an Application, filed February 3, 2009.

This Petition is hereby **dismissed**.

Any further petition must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Request for Reconsideration of Petition under [insert the applicable code section]". This is **not** final agency action within the meaning of 5 U.S.C. § 704.

Background

Petitioner files the present petition to expunge the assignment record of the present patent. Petitioner provides that the Change of Name Recordation and Assignment of Assignors Interest were unintentionally submitted and would cause irreparable harm to the party in interest on whose behalf the information was submitted. Petitioner further states that the information requested to be expunged is not material information under 37 CFR 1.56.

Initially it is noted that in recording assignment (merger and change of name) documents, the Office does not determine whether the document is valid, nor does the Office determine the effect of the document. It is also noted that it is appropriate to file merger documents. The MPEP 314, Certificates of Change of Name or of Merger, provides

> Certificates issued by appropriate authorities showing a change of name of a business or a merger of businesses are recordable. Although a mere change of name does not constitute a change in legal entity, it is properly a link in the chain of title. Documents of

merger are also proper links in the chain of title. They may represent a change of entity as well as a change of name.

Regarding expungement of assignment records, the MPEP 323.01(d), Expungement of Assignment Records, states:

> Petitions to correct, modify or "expunge" assignment records are rarely granted. Such petitions are granted only if the petitioner can prove that:
> (A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
> (B) the integrity of the assignment records will not be affected by granting the petition.
>
> Even if a petition to "expunge" a document is granted with respect to a particular application or patent, the image of the recorded document will remain in the records of the Assignment Services Division at the same reel and frame number, and the image will appear when someone views that reel and frame number. The Office will, however, delete the links to the application or patent that was the subject of the petition, so that no information about the recorded document will appear when someone searches for that application or patent number in the Assignment Historical Database.

Here, Applicant has failed to demonstrate that the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief, and that the integrity of the assignment records will not be affected by granting the Petition.

The petition is dismissed without prejudice. Petitioner should file a request for reconsideration of petition and include the necessary showing.

Further correspondence with respect to this matter should be addressed as follows:

By mail:	Director for Patents PO Box 1450 Alexandria, VA 22313-1450
By FAX:	(571) 273-8300 Attn: Office of Petitions
By hand:	Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Telephone inquiries concerning this petition Decision should be directed to the undersigned at (571) 272-3232.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

COMPLETED

Dr. Tahira Hamlet-Cox
Intellectual Property for Incyte Corporation
1360 Porter Drive
Palo Alto CA 94304

COPY MAILED

MAR 16 2009

OFFICE OF PETITIONS

In re Application of	:	
Tang et al.	:	
Application No. 06/308184	:	DECISION ON PETITION
Filing or 371(c) Date: 09/28/1981	:	
Patent Number: 6958725	:	
Issue Date: 10/25/2005	:	
Title of Invention:	:	
RADOME ABERRATION CORRECTING SYSTEM	:	

This is a Decision in response to the Petition Under 37 C.F.R. § 1.59(b) to Expunge Information Unintentionally Submitted in an Application, filed February 3, 2009.

This Petition is hereby **dismissed**.

Any further petition must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Request for Reconsideration of Petition under [insert the applicable code section]". This is **not** final agency action within the meaning of 5 U.S.C. § 704.

Background

Petitioner files the present petition to expunge the assignment record of the present patent. Petitioner provides that the Change of Name Recordation and Assignment of Assignors Interest were unintentionally submitted and would cause irreparable harm to the party in interest on whose behalf the information was submitted. Petitioner further states that the information requested to be expunged is not material information under 37 CFR 1.56.

Initially it is noted that in recording assignment (merger and change of name) documents, the Office does not determine whether the document is valid, nor does the Office determine the effect of the document. It is also noted that it is appropriate to file merger documents. The MPEP 314, Certificates of Change of Name or of Merger, provides

> Certificates issued by appropriate authorities showing a change of name of a business or a merger of businesses are recordable. Although a mere change of name does not constitute a change in legal entity, it is properly a link in the chain of title. Documents of

merger are also proper links in the chain of title. They may represent a change of entity as well as a change of name.

Regarding expungement of assignment records, the MPEP 323.01(d), Expungement of Assignment Records, states:

> Petitions to correct, modify or "expunge" assignment records are rarely granted. Such petitions are granted only if the petitioner can prove that:
> (A) the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief; and
> (B) the integrity of the assignment records will not be affected by granting the petition.
>
> Even if a petition to "expunge" a document is granted with respect to a particular application or patent, the image of the recorded document will remain in the records of the Assignment Services Division at the same reel and frame number, and the image will appear when someone views that reel and frame number. The Office will, however, delete the links to the application or patent that was the subject of the petition, so that no information about the recorded document will appear when someone searches for that application or patent number in the Assignment Historical Database.

Here, Applicant has failed to demonstrate that the normal corrective procedures outlined in MPEP § 323.01(a) through § 323.01(c) will not provide the petitioner with adequate relief, and that the integrity of the assignment records will not be affected by granting the Petition.

The petition is dismissed without prejudice. Petitioner should file a request for reconsideration of petition and include the necessary showing.

Further correspondence with respect to this matter should be addressed as follows:

By mail:	Director for Patents PO Box 1450 Alexandria, VA 22313-1450
By FAX:	(571) 273-8300 Attn: Office of Petitions
By hand:	Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Telephone inquiries concerning this petition Decision should be directed to the undersigned at (571) 272-3232.

/Derek L. Woods/
Derek L. Woods
Attorney
Office of Petitions

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 17

DANIEL SIXBEY
SIXBEY FRIEDMAN LEEDOM & FERGUSON PC
8180 GREENSBORO DRIVE SUITE 800
McLEAN VIRGINIA 22102

COPY MAILED

APR 2 1 2000

SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS

In re Patent No. 4,425,908 :
Issue Date: January 17, 1984 :
Application No. 06/314,005 : ON PETITION
Filed: January 17, 1984 :
Inventor: Morris Simon :

This is a decision on the petition, filed September 21, 1999, under 37 CFR 1.378(e) requesting reconsideration of a prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-identified patent.

The request to accept the delayed payment of the maintenance fee under 37 CFR 1.378(b) is DENIED.

BACKGROUND

The patent issued January 17, 1984. The first and second maintenance fees were timely paid. Accordingly, the third maintenance fee due could have been paid during the period from January 17, 1995 through July 17, 1995, or with a surcharge during the period from July 18, 1995 through January 17, 1996. The above-identified patent expired as of midnight, January 17, 1996.

A petition under 37 CFR 1.378(b) to accept late payment of the first maintenance fee was filed November 10, 1998, and was dismissed in the decision of July 21, 1999.

STATUTE AND REGULATION

35 U.S.C. § 41(c)(1) states that:

> "The Commissioner may accept the payment of any maintenance fee required by subsection (b) of this section... after the six-month grace period if the delay is shown to the satisfaction of the Commissioner to have been unavoidable."

37 CFR 1.378(b)(3) states that any petition to accept delayed payment of a maintenance fee must include:

> "A showing that the delay was unavoidable since reasonable care was taken to ensure that the maintenance fee would be paid timely and that the petition was filed promptly after the patentee was notified of, or otherwise became aware of, the expiration of the patent. The showing must enumerate the steps taken to ensure timely payment of the maintenance fee, the date, and the manner in which patentee became aware of the expiration of the patent, and the steps taken to file the petition promptly."

OPINION

The Commissioner may accept late payment of the maintenance fee if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable"; 35 USC 41(c)(1).

Petitioner (Nitinol, the assignee) requests reconsideration in that (1) Nitinol relied upon the firm of Nixon & Vanderhye (Nixon) and its docketing system, as petitioner contends that Nixon's counsel constitutes petitioner's attorneys of record, for maintenance fee payments, (2) Nixon has been contacted by petitioner regarding this matter but has declined to offer information or assistance, (3) Nixon apparently contends that Nixon was engaged by petitioner solely for proceedings relating to the patent term extension request (filed in 1990), (4) counsel presenting the instant petition has represented petitioner for maintenance fee payments in other patents, but was not engaged for this patent. As such, petitioner asserts, the silence of Nixon should not operate to the detriment of Nitinol, and the patent reinstated.

Petitioner has not carried the burden of proof to establish to the satisfaction of the Commissioner that the delay was unavoidable.

Acceptance of late payment of a maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 USC 133 because 35 USC 41(c)(1) uses the identical language, i.e. "unavoidable delay". Ray v. Lehman, 55 f. 3d 606, 608-09, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995)(quoting In re Patent No. 4,409,763, 7 USPQ2d 1798, 1800 (Comm'r Pat.

1988)). Decisions on reviving abandoned applications have adopted the "reasonably prudent person" standard in determining if the delay in responding to an Office action was unavoidable. Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (Comm'r Pat. 1887)(the term "unavoidable" "is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business"); In re Mattullath, 38 App. D.C. 497, 514-515 (D.C. Cir. 1912); and Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141. In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account." Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C. Cir. 1982). Finally, a petition to revive an application as unavoidably abandoned cannot be granted where a petitioner has failed to meet his or her burden of establishing the cause of the unavoidable delay. Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

Petitioner is reminded that it is the patentee's burden under the statutes and regulations to make a showing to the satisfaction of the Commissioner that the delay in payment of a maintenance fee is unavoidable. See Rydeen v. Quigg, 748 F. Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), aff'd 937 F.2d 623 (Fed. Cir. 1991)(table), *cert. denied*, 502 U.S. 1075 (1992); Ray v. Lehman, supra.

In determining whether a delay in paying a maintenance fee was unavoidable, one looks to whether the party responsible for payment of the maintenance fee exercised the due care of a reasonably prudent person. Ray, 55 F3d at 608-609, 34 USPQ2D at 1787. It is incumbent upon the patent owner to implement steps to schedule and pay the fee, or obligate another to do so. See California Medical Products v. Technol. Med. Prod., 921 F.Supp 1219, 1259 (D. Del. 1995). The patent owner must demonstrate that the patent had been docketed in a docketing system as would have been relied upon by a prudent and careful person with respect to that person's most important business. Id. In this regard, the record does not adequately show, as noted in the previous decision, that Nixon had ever been engaged by petitioner to track the maintenance fee payment, much less make the payment on behalf of petitioner. Even assuming in a light most favorable to petitioner that his patent term extension firm (Nixon) had assumed that obligation, reliance *per se* upon another to track and pay maintenance fees does not provide a petitioner with a showing of unavoidable delay within the meaning of 37 C.F.R. 1.378(b) and 35 U.S.C. 41(c). Id. Rather, such reliance merely

shifts the focus of the "reasonably prudent" inquiry from petitioner to the appointed representative. Id. Nevertheless, petitioner is bound by any errors that may have been committed by that representative. Id.

However, as petitioner has failed to establish who it had engaged to pay the maintenance fees, then petitioner had to have provided a showing that it had such steps in place as would be employed by a prudent and careful person, to ensure timely payment of the maintenance fees. Id. However, petitioner apparently took no steps on its own, as it believed, apparently through miscommunication, that it had appointed Nixon to undertake that obligation. In this regard, if Nixon had assumed the obligation to track and/or pay the maintenance fee, then petitioner would have been able to produce its own records to that effect, notwithstanding Nixon's silence.

Nevertheless, delay resulting from a lack of proper communication between a patentee and that patentee's representative(s) as to the responsibility for scheduling and payment of a maintenance fee does not constitute unavoidable delay within the meaning of 35 USC 41(c) and 37 CFR 1.378(b). See, In re Kim, 12 USPQ2d 1595 (Comm'r Pat. 1988). Specifically, delay resulting from a failure in communication between a patent holder and his representative regarding a maintenance fee payment is not unavoidable delay within the meaning of 35 USC 41(c) and 37 CFR 1.378(b). Ray, 55 F.3d at 610, 34 USPQ2d at 1789. That all parties failed to take adequate steps to ensure that each fully understood the other party's meaning, and thus, their own obligation in this matter, does not reflect the due care and diligence of prudent and careful persons with respect to their most important business within the meaning of Pratt, supra.

Petitioner is advised that delay resulting from a lack of awareness of the need to pay maintenance fees, or delay resulting from petitioner's lack of receipt of any maintenance fee reminder(s), or petitioner's being unaware of the need for maintenance fee payments, does not constitute "unavoidable" delay. See Patent No. 4,409,763, supra, *aff'd*, Rydeen v. Quigg, supra. See also "Final Rules for Patent Maintenance Fees," 49 *Fed. Reg.* 34716, 34722-23 (Aug. 31, 1984), reprinted in 1046 *Off. Gaz. Pat. Office* 28, 34 (September 25, 1984). Under the statutes and regulations, the Office has no duty to notify patentee of the requirement to pay maintenance fees or to notify patentee when the maintenance fee is due. While the Office mails maintenance

fee reminders strictly as a courtesy, it is solely the responsibility of the patentee to ensure that the maintenance fee is timely paid to prevent expiration of the patent. The failure to receive the Reminder does not relieve the patentee of the obligation to timely pay the maintenance fee, nor will it constitute unavoidable delay if the patentee seeks reinstatement under the regulation. Rydeen, Id. Moreover, a patentee who is required by 35 USC 41(c)(1) to pay a maintenance fee within 3 years and six months of the patent grant, or face expiration of the patent, is not entitled to any notice beyond that provided by publication of the statute. Id. at 900, 16 USPQ2d at 1876.

Furthermore, the Letters Patent contains a Maintenance Fee Notice that warns that the patent may be subject to maintenance fees if the application was filed on or after December 12, 1980. While the record is not clear as to whether petitioner ever read the Maintenance Fee Notice, petitioner's failure to read or remember the Notice does not vitiate the Notice, nor does the delay resulting from such failure to read the Notice establish unavoidable delay. Ray, 55 F.3d at 610, 34 USPQ2d at 1789. The mere publication of the statute was sufficient notice to petitioner. Rydeen, supra.

Petitioner is reminded that the Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the applicant, and applicant is bound by the consequences of those actions or inactions. Link v. Wabash, 370 U.S. 626, 633-34 (1962); Huston v. Ladner, 973 F.2d 1564, 1567, 23 USPQ2d 1910, 1913 (Fed. Cir. 1992); see also Haines v. Quigg, 673 F. Supp. 314, 317, 5 USPQ2d 1130, 1132 (D.N. Ind. 1987). Specifically, petitioner's delay caused by the mistakes or negligence of his voluntarily chosen representative does not constitute unavoidable delay within the meaning of 35 USC 133. Haines v. Quigg, supra; Smith v. Diamond, 209 USPQ 1091 (D.D.C. 1981); Potter v. Dann, 201 USPQ 574 (D.D.C. 1978); Ex parte Murray, 1891 Dec. Comm'r Pat. 130, 131 (Comm'r Pat. 1891). As such, assuming that petitioner had engaged Nixon for payment of the maintenance fees of the above identified patent, then it was incumbent upon petitioner to demonstrate, via a documented showing, that his duly appointed representative had docketed this patent for the first maintenance fee payment in a reliable tracking system. Id. However, petitioner has not been able to demonstrate that the patent was docketed for payment of the maintenance fees, or that Nixon had assumed that obligation on behalf of petitioner.

Even assuming that such a document(s) existed, and had been made of record, petitioner has also failed to demonstrate why petitioner's failure to diligently monitor Nixon's performance under the putative contract can reasonably be considered to constitute unavoidable delay. See Futures Technology Ltd. v. Quigg, 684 F.Supp. 430, 7 USPQ2d 1588 (E.D. Va. 1988). That is, petitioner's apparent failure to monitor Nixon's performance under the alleged contract, or diligently inquire of Nixon, or anyone else, including the PTO, into the status of the patent and maintenance fee payment, does not reflect the due care and diligence employed by a prudent and careful person with respect to their most important business, and as such, cannot demonstrate that the delay was unavoidable delay. Id. Rather, a prudent person takes diligent action to ensure that contracted services are timely performed as specified. Id. Note further in this regard, that the record does not present any invoice(s) from Nixon for services rendered with respect to tracking the maintenance fee payment, much less for the payment itself. The record lacks any showing that Nixon ever represented to petitioner that the maintenance fee had been paid, much less that petitioner ever paid Nixon for services rendered with respect to the maintenance fee payment. There is no showing from petitioner's records which were in *his* and not Nixon's possession, that petitioner, upon *timely* discovering that Nixon had not yet presented petitioner with an itemized bill for payment of the fee, diligently inquired of Nixon as to why that allegedly contracted service had not been timely discharged, in time to prevent expiration of the patent, or more diligently present a petition seeking reinstatement.

Even assuming, *arguendo*, that Nixon had been obligated in this matter, and further, that petitioner would not be bound by the mistakes or omissions of Nixon, diligence on the part of petitioner would still be essential to show unavoidable delay. See, Douglas v. Manbeck, 21 USPQ2d 1697, 1699-1700 (E.D. Pa. 1991), *aff'd*, 975 F.2d 869, 24 USPQ2d 1318 (Fed. Cir. 1992) (applicant's lack of diligence over a two and one half year period in taking any action with respect to his application, precluded a finding of unavoidable delay). However, the record lacks an adequate showing of petitioner's diligence in this matter during the entire period extending from the last date that the maintenance fee could have been timely filed (the one year period year that ended January 17, 1996), until the filing of the first petition on November 10, 1998, a period of almost three (3) years, which would be necessary to support a finding of

unavoidable delay. Id. Specifically, diligence on the part of the owner is necessary to show unavoidable delay when that owner's putative agent(s) fails to take timely and proper steps with respect to a proceeding before the Patent and Trademark Office. Futures, 684 F.Supp. 430 at 431, 7 USPQ2d at 1589. However, petitioner has not shown diligence with respect to any aspect of the payment of the maintenance fee for this patent. Petitioner's lack of due diligence with respect to this patent, for a period of time of almost three (3) years, overcame and superseded any omissions or commissions by his representative(s). Douglas, supra; Haines v. Quigg, supra. The delay was not unavoidable, because had petitioner exercised the due care of a reasonably prudent person, petitioner would have been able to act to correct the situation in a timely fashion. Haines v. Quigg, supra; Douglas, supra.

Petitioner's request for relief, notwithstanding the admitted lack of a showing from Nixon, cannot be favorably considered. it is brought to petitioner's attention that the requirement for a showing of unavoidable delay is a requirement of the statute (35 USC 41(c)), and, as such, the PTO lacks the authority or discretion to waive that requirement. See In Re Patent No. 4,409,763, 7 USPQ2d 1798, 1802 (Comm'r Pat. 1988), *aff'd*, Rydeen v. Quigg, 748 F. Supp. 900, 16 USPQ2d 1876 (D.D.C. 1990), *aff'd* 937 F.2d 623 (Fed. Cir. 1991)(table), *cert. denied*, 502 U.S. 1075 (1992). It follows that whatever principles might be enlisted by or on behalf of petitioner, such principles cannot properly be employed to offset the lack herein of an adequate showing of unavoidable delay. Rather, the decision of the PTO on the question of whether the delay herein was unavoidable *vel non* can only be based on the contents of the administrative record in this case. Douglas v. Manbeck, supra; Haines v. Quigg, supra. As noted above, the administrative record in this case lacks the necessary showing to meet petitioner's burden of proving that the entire delay herein was unavoidable. The record fails to adequately evidence that either petitioner or Nixon exercised the due care observed by prudent and careful men, in relation to their most important business, which is necessary to establish unavoidable delay. Pratt, supra. In the absence of a showing of the steps emplaced to pay the maintenance fees, then 37 CFR 1.378(b) does not permit acceptance of the belated fee.

As also noted in the previous decision, the PTO is simply not the forum for resolving a dispute between a patentee and his putative representative(s) regarding an unpaid maintenance fee. Ray,

supra. Moreover, there is no need in this case to determine the obligation between Nixon and petitioner, since the record fails to show that either Nixon or petitioner took adequate steps to ensure timely payment of the maintenance fee. See In re Patent No. 4,461,759, 16 USPQ2d 1883, 1884 (Comm'r Pat. 1990).

DECISION

The prior decision which refused to accept under § 1.378(b) the delayed payment of a maintenance fee for the above-identified patent has been reconsidered. For the above stated reasons, however, the delay in this case cannot be regarded as unavoidable within the meaning of 35 USC 41(c) and 37 CFR 1.378(b).

As stated in 37 CFR 1.378(e), no further reconsideration or review of this matter will be undertaken.

Since this patent will not be reinstated, the maintenance fees and the surcharge submitted by petitioner totaling $3860, have been credited to deposit account No. 19-2380. The $130 fee under 37 CFR 1.17(h) for requesting reconsideration (non-refundable) has been charged to the same account.

Lastly, the revocation and power of attorney filed with the instant petition has not been accepted as it lacks a certification under 37 CFR 3.73(b). If the request is renewed with a certification, it should be directed to the Office of Public Records, Dissemination Support Branch, Records Branch, at the PTO's usual mailing address. See MPEP 2560.

The patent file is being returned to the Files Repository.

Telephone inquiries regarding this decision should be directed to Petitions Examiner Brian Hearn at (703) 305-1820.

Manuel A. Antonakas, Director,
Office of Petitions

cc: NIXON & VANDERHYE
1100 NORTH GLEBE ROAD, 8th FLOOR
ARLINGTON VA 22201-4714

CC: SYLVIA BOYD
PO BOX 1050
CAMBRIDGE MA 02238

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Jeffrey J. Hohenshell
Senior Patent Attorney
Medtronic Cardiac Surgery Division
7601 Northland Dr.
Brooklyn Park, MN 55428

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DEC 29 2005

OFFICE OF PETITIONS

In re Application of :
Wright, et al. : DECISION ON PETITION
Application No. 06/316,203 :
Filed: October 29, 1981 :
Docket No.: VCR-8 :

This is a decision on the petition under 37 CFR 1.137(b), filed November 3, 2005, and supplemented November 21, 2005, to revive the above-identified application.

The petition is **GRANTED**.

This application became abandoned August 18, 2005 for failure to timely submit the issue fee in response to the Notice of Allowance and Issue Fee(s) Due ("Notice") mailed May 17, 2005. The Notice set a three month statutory period for reply. Notice of Abandonment was mailed November 4, 2005.

A grantable petition pursuant to 37 C.F.R. § 1.137(b) must be accompanied by: (1) the required reply to the outstanding Office action or notice, unless previously filed; (2) the petition fee as set forth in 37 C.F.R. § 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional; and (4)any terminal disclaimer (and fee set forth in 37 C.F.R. § 1.20(d)) required pursuant to 37 C.F.R. § 1.137(c).

The instant petition has been reviewed and found in compliance with the provisions of 37 CFR 1.137(b). Accordingly, the failure to timely submit a proper reply to the Notice is accepted as having been unintentionally delayed.

This application will be forwarded to the Publications Division for further processing.

Telephone inquiries concerning this matter may be directed to the undersigned at (571) 272-3205.

Alesia M. Brown
Petitions Attorney
Office of Petitions

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Brooklyn Park, MN 55428

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APR 30 2007

OFFICE OF PETITIONS

In re Application of
Wright et al.
U.S. Patent No. 7,018,407
Issue Date: March 28, 2006
Application No. 06/316,203
Filed: October 29, 1982
For: VALVE HOLDER FOR TRICUSPID HEART VALVE

Letter For
Certificate of Correction

The above-identified application has been forwarded to the undersigned for correction of the patent term extension information printed on the front page of the patent. In a telephone call with Jeffrey Hohenshell on April 27, 2007, it was confirmed that the Office would request a certificate of correction to correct the patent term extension information printed on the face of the patent. See 35 U.S.C. § 154(b)[1] and 37 C.F.R. § 1.701.

The Notice of Allowance and Issue Fee Due mailed on May 17, 2005, correctly indicated that the patent to issue from Application No. 06/316,203 was not eligible for a patent term extension, as the application was filed before June 8, 1995. The front page of the patent incorrectly indicates that the term of the patent is extended for 1109 days. Since the filing date was before June 8, 1995, the patent to issue from the application is eligible only for a 17-year term, which does not permit a patent term extension.

After mailing of this letter, the Office will issue a certificate of correction in order to rectify the error regarding the patent term extension information. See 35 U.S.C. 254 and 37 CFR 1.322. The Office will issue a certificate of correction deleting the patent term extension information.

Telephone inquiries with regard to this communication should be directed to the undersigned at (571) 272-7709.

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

[1] 35 U.S.C. § 154 was amended by the "American Inventors Protection Act of 1999," which was enacted on November 29, 1999 as part of Public Law 106-113 (Consolidated Appropriations Act for Fiscal Year 2000). Since this amendment is effective May 29, 2000 and applies to applications filed on or after that date, the existing patent term adjustment provisions of 35 U.S.C. § 154 continue to apply to the above-identified application.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 7,018,407

DATED : March 28, 2006

INVENTOR(S) : Wright et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page,
[*] delete "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1109 days."

NOTICE RE: CERTIFICATES OF CORRECTION

DATE : **January 2, 2001**

Paper No.: **24**

TO : Supervisor, Art Unit **1600** 1614

SUBJECT : Certificate of Correction Request in Patent No.: **4,420,639**

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

[X] 1. Would the change(s) requested, under 37 C.F.R. 1.323, correcting Applicant/Attorney's (A or Atty.) errors, constitute new matter or require reexamination of the application? **Note corrections to Related U. S. Application Data on PTOL 1050 form (stapled to CONTENTS page).**

[ ] 2. Would the change(s) requested, under 37 C.F.R. 1.323, correcting Applicant/Attorney's (A or Atty.) errors, materially affect the scope or meaning of the claims allowed by the examiner in the patent?

[ ] 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Should the change request be granted?

[ ] 4. With respect to the change(s) requested, correcting Office and/or printing (O, Off, C, and/or P) errors, should the patent read as shown in the certificate of correction?

[ ] 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO PALM LOCATION. 7580, CERTIFICATES OF CORRECTION BR, PARK 3 -922, Thank you

Cecelia Newman

Lead Legal Instrument Examiner
Tel. No. 305-8228

PLEASE CHECK THE BOX(ES) BELOW CORRESPONDING TO THE BOXES CHECKED FOR QUESTION(S) ABOVE AND RETURN FILE TO: PALM LOCATION 7580, CERT. OF CORREC. BR., PK 3 - 918

DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

[ ] 1.YES	[X] NO	[ ] Comments below
[ ] 2.YES	[ ] NO	[ ] Comments below
[ ] 3.YES	[ ] NO	[ ] Comments below
[ ] 4.YES	[ ] NO	[ ] Comments below
[ ] 5.YES	[ ] NO	[ ] Comments below

[ ] Comments _____

_____ 1614

Supervisor Art Unit

1/87) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

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WASHINGTON, D.C. 20231
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FEB 15 2001

#19

James J. Sales
ELI LILLY AND COMPANY
Patent Division/jjs Lilly Corporate Center
INDIANAPOLIS IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

Dear Mr. Sales:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: EVISTA
FDA Docket No.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 4,418,068 : INTERIM EXTENSION

Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156 on January 20, 1998. The original term of the patent is due to expire on April 3, 2001. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on December 9, 1997. An extension of 1,103 days is requested.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by FDA. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the original expiration date of the patent, until April 3, 2002.

JAN 30 2001
Date

Nicholas P. Godici
Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

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REEXAM UNIT

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

#22

James J. Sales
Eli Lilly and Company
Patent Division/jjs Lilly Corporate Center
Indianapolis IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

Dear Mr. Sales:

A order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: EVISTA®
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,418,068	:	**INTERIM EXTENSION**

Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156. An extension of 1,103 days is requested, and an interim extension under 35 U.S.C. § 156(e)(2) has been previously granted for a period of one year. The patent is eligible for an extension of at least two years. The expiration date of the patent, as previously extended, is April 3, 2002. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, as previously extended, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the extended expiration date of the patent, until April 3, 2003.

MAR - 7 2002
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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WILLIAM H MEISE
DUANE MORRIS LLP
PO BOX 5203
PRINCETON NJ 08543-5203

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AUG 0 6 2007

OFFICE OF PETITIONS

In re Application of :
Samuel M. Sherman :
Application No. 06/334,832 : ON PETITION
Filed: December 23, 1981 :
Attorney Docket No. RCA77153 :

This is a decision on the petition to revive under 37 CFR 1.137(a), filed June 28, 2007.

The petition under 37 CFR 1.137(a) is **GRANTED**.

The above-identified application became abandoned for failure to reply to the Notice of Allowance mailed July 21, 2006. This Notice set a statutory period for reply of three (3) months for issue fee transmittal. No issue fee having been received, the application became abandoned on October 22, 2006. A Notice of Abandonment was mailed on May 21, 2007.

A grantable petition under 37 CFR 1.137(a) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(l); (3) a showing to the satisfaction of the Commissioner that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(a) was unavoidable; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required pursuant to 37 CFR 1.137(d). Decisions on reviving abandoned applications on the basis of "unavoidable" delay have adopted the reasonably prudent

person standard in determining if the delay was unavoidable:

> The word 'unavoidable' . . . is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business. It permits them in the exercise of this care to rely upon the ordinary and trustworthy agencies of mail and telegraph, worthy and reliable employees, and such other means and instrumentalities as are usually employed in such important business. If unexpectedly, or through the unforeseen fault or imperfection of these agencies and instrumentalities, there occurs a failure, it may properly be said to be unavoidable, all other conditions of promptness in its rectification being present.[1]

Moreover, a petition cannot be granted where a petitioner has failed to meet his or her burden of establishing that the delay was "unavoidable."[2]

A review of the application reveals that the Notice of Allowance was returned as undeliverable due to an error on the part of the Office.

In view of the above, it is concluded that petitioner has met his burden of establishing that the delay was unavoidable.

Receipt of the petition fee, issue fee, and terminal disclaimer fee is acknowledged.

The matter is being forwarded to the Office of Patent Publication for processing into a patent.

Telephone inquiries concerning this decision should be directed to the undersigned at (571)272-3207.

Cliff Congo
Petitions Attorney
Office of Petitions

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[1] In re Mattullath, 38 App. D.C. 497, 514-15 (1912)(quoting Ex parte Pratt, 1887 Dec. Comm'r Pat. 31, 32-33 (1887)); see also Winkler v. Ladd, 221 F. Supp. 550, 552, 138 USPQ 666, 167-68 (D.D.C. 1963), aff'd, 143 USPQ 172 (D.C. Cir. 1963); Ex parte Henrich, 1913 Dec. Comm'r Pat. 139, 141 (1913).

[2] Haines v. Quigg, 673 F. Supp. 314, 316-17, 5 USPQ2d 1130, 1131-32 (N.D. Ind. 1987).

UNITED STATES PATENT AND TRADEMARK OFFICE

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#16

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DEC 3 1 2001

OFFICE OF PETITIONS

Charles E. Van Horn
Finngan Henderson Farabow Garrett & Dunner LLP
1300 I Street NW
Washington DC 20005

In re
Application for Patent Term Extension
U.S. Patent No. 4,386,085
For: MIFEPREX®

Dear Mr. Van Horn:

The above-identified patent has been extended under 35 U.S.C,. § 156(e)(2) for a period of one year. A copy of the order granting the interim extension is enclosed.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

FDA Docket No. 01E-0363
Attorney Docket No. 08292.001

UNITED STATES PATENT AND TRADEMARK OFFICE

In re The Population Council, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,386,085	:	**INTERIM EXTENSION**

On November 22, 2000, The Population Council, Inc., the owner of record of U.S. Patent No. 4,386,085, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of U.S. Patent No. 4,386,085. An extension of five years is requested. The patent claims the active ingredient, mifepristone, in the human drug product "MIFEPREX®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. The original term of the patent expires on January 8, 2002.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,386,085 is granted for a period of one year from the original expiration date of the patent.

DEC 28 2001
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

JAN 8 2003

Charles E. Van Horn
Finngan Henderson Farabow Garrett & Dunner LLP
1300 I Street NW
Washington DC 20005

Re: Patent Term Extension
Application for
U.S. Patent No. 4,386,085

Dear Mr. Van Horn:

A order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,386,085 for a period of one year is attached. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format (with updated contact information) for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MIFEPREX™ (mifepristone)
FDA Docket No.: 01E-0363

UNITED STATES PATENT AND TRADEMARK OFFICE

In re The Population Council, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,386,085	:	**INTERIM EXTENSION**

On November 22, 2000, The Population Council, Inc., the owner of record of U.S. Patent No. 4,386,085, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of the patent. An extension of five years is requested. An interim extension for a period of one year has already been granted. The patent claims the active ingredient, mifepristone, in the human drug product "MIFEPREX®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. The extended term of the patent expires on January 8, 2003.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, a second interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,386,085 is granted for a period of one year from the extended expiration date of the patent, until January 8, 2004.

JAN - 7 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Official

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

MAR 1 5 2002

REEXAM UNIT

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WASHINGTON, D.C. 20231
www.uspto.gov

#23

David J. Josephic
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati OH 45202-2917

Re: Patent Term Extension Application for U.S. Patent No. 4,490,351

Dear Mr. Josephic:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,490,351 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: VITREON®
FDA Docket No.: 98E-0849

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Vitrophage, Inc. :
Request for Patent Term Extension : **ORDER GRANTING**
U.S. Patent No. 4,490,351 : **INTERIM EXTENSION**

On November 22, 2000, Vitrophage, Inc., the owner of record of U.S. Patent No. 4,490,351, filed an application under 35 U.S.C. § 156(d)(1) for extension of the term of U.S. Patent No. 4,490,351. An extension of five years is requested. The patent claims a method of use of the approved device, perfluorophenanthrene ("VITREON®"). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product. The original term of the patent expires on March 15, 2002.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,490,351 is granted for a period of one year from the original expiration date of the patent, i.e., until March 15, 2003.

MAR - 7 2002
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

MAR 13 2003

#24

David J. Josephic
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati OH 45202-2917

Re: Patent Term Extension
Application for
U.S. Patent No. 4,490,351

Dear Mr. Josephic:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,490,351 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: VITREON®
FDA Docket No.: 98E-0849

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Vitrophage, Inc.	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,490,351	:	**INTERIM EXTENSION**

Vitrophage, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,490,351, filed an application under 35 U.S.C. § 156(d)(1), requesting an extension of five years. The original expiration date of the patent was March 15, 2002, and an interim extension of one year has previously been granted pursuant to 35 U.S.C. 156(e)(2), extending the patent to March 15, 2003. The patent claims a method of use of the approved device, perfluorophenanthrene ("VITREON®"). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product. The term of the patent, as previously extended, expires on March 15, 2003.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, a second interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,490,351 is granted for a period of one year from the extended expiration date of the patent, i.e., until March 15, 2004.

MAR 11 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON, TX 77056

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NOV 1 2 2008

OFFICE OF PETITIONS

In re Patent No. 4,507,914 :
Issue Date: April 2, 1985 :
Application No. 06/416,275 : ON PETITION
Filed: September 9, 1982 :
Attorney Docket No. RICE/0004 :

This is a decision on the petition under 37 CFR 1.182, filed September 4, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **granted**.

The Office of Data Management is directed to issue duplicate Letters Patent.

A copy of this decision is being forwarded to the Office of Data Management for issuance of the duplicate Letters Patent.

The patent file is being referred to the Files Repository.

Any questions concerning this matter may be directed to the undersigned at (571) 272-3226. Any questions concerning issuance of the duplicate Letters Patent should be directed to Niomi Farmer at (703) 308-9250 ext 119.

Andrea Smith
Petitions Examiner
Office of Petitions

cc: Niomi Farmer, P/OPPD, South Tower 8th Floor, Room C23
FAX No. (571) 270-9753

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 27 2008

Dianna Goldenson
Darby & Darby
805 Third Ave.,
New York, NY 10022-7513

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,560,766

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 4,560,766

This is in response to the application for extension of the term of U.S. Patent No. 4,560,766 ("the '766 patent") under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on August 30, 2000, the request for interim extension filed on February 5, 2007, and the request for reconsideration, filed on September 28, 2007. The application was filed by Lonza Inc. ("Applicant"). Extension is sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act of the food additive known as Dantobrom®RW/Dantochlor®RW, which was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 30, 2000. Because the application for patent term extension ("PTE application") was not timely filed, Applicant's request for extension of the patent term of the '766 patent is **DENIED**, the request for interim extension is **DENIED**, and its request for reconsideration is **DENIED**. Additionally, the four interim extensions previously granted under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

A. Decision

1. For Purposes of Patent Term Extension for a Food Additive, Permission for Commercial Marketing or Use is Under the FFDCA and Occurs When the Food Additive Regulations Are Amended

Applicant argues that the patented product Dantobrom®RW/Dantochlor®RW required regulatory review under the FFDCA as administered by FDA and under FIFRA as administered by the Environmental Protection Agency (EPA). Applicant argues that because additional regulatory review was required under FIFRA, the approval by FDA, in the form of amending the food additive regulations, did not amount to permission to commercially market or use Dantobrom®RW/Dantochlor®RW.

It is understood that the Federal Register notice which amended the food additive regulations to provide for the safe use of Dantobrom®RW/Dantochlor®RW as a slimicide in the manufacture of paper and paperboard intended to contact food, also indicated that further regulatory review under FIFRA may be required. However, even if additional regulatory review by another government agency was required the statutory language of § 156(d)(1) is clear as to

when the sixty day period begins for submitting an application for patent term extension. The specific statutory language in section 156(d)(1) states:

> To obtain an extension of the term of a patent under this section, the owner or record or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.

(Emphasis added.)

The word "permission" cannot be read in a context that excludes "under the provision of law under which the applicable regulatory review period occurred." Thus, whether Applicant could commercially market or use Dantobrom®RW/Dantochlor®RW based solely on FDA amending the food additive regulations is irrelevant to determining compliance with the requirement that an application for patent term extension be submitted within the sixty day period beginning on the date the product (here, Dantobrom®RW/Dantochlor®RW) received "permission" for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred (here, Section 409 of FFDCA). In other words, further additional regulatory review by another government agency is irrelevant to determining compliance with the sixty day period set forth in § 156(d)(1) since the critical triggering event relates to permission under the provision of law under which the "applicable regulatory review period" occurred, which, for a food additive, is set forth in § 156(g)(2)(B)(i) and § 156(g)(2)(B)(ii). Although an additional regulatory review period may have been necessary to commercially market the product for its intended end use, a regulatory review period under FIFRA is not contemplated by the statute. Since the only regulatory review period relevant to triggering the sixty day window for submitting a PTE application for a food additive is in accordance with Section 156(g)(2)(B)(ii), the date which began the sixty day period for Dantobrom®RW/Dantochlor®RW is June 30, 2000 (the date of the Federal Register notice amending 21 C.F.R. § 176). Accordingly, since the PTE application was submitted on August 30, 2000, it is untimely and hence, the PTE application is **DENIED**.

2. Judicial Precedent Directed to NDA Approvals Is Applicable to Other Regulated Products Subject to a Regulatory Review Period as Defined in 35 U.S.C. § 156(g)

Applicant argues that the judicial precedent cited in the Notice of Final Determination-Ineligible, directed to NDA approvals where additional regulatory review by DEA, is not relevant to the additional regulatory review by EPA under FIFRA for Dantobrom®RW/Dantochlor®RW. The USPTO does not agree with this assessment. While it is true that FDA reviews and approves these types of products under different regulatory schemes, 21 C.F.R. § 314 for drug products and 21 C.F.R. § 171 for food additives, the statutory requirements under Section 156 for patent term extension for drug products and food additives are the same. For determining the amount of

term to be extended, Section 156(g)(1) indicates the regulatory review period for a drug product, Section 156(g)(2) indicates the regulatory review period for a food additive, and all other sections of § 156 are applicable across the board regardless of the type of product subject to regulatory review, i.e., paragraphs (a)(1)-(5) and paragraph (d)(1). Accordingly, as stated by the court in *Mead Johnson Pharm Group v Bowen*, 838 F.2d 1332 (D.C. Cir 1988) and *Unimed Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989), the approval which triggers the start of the sixty day period for submission of an application for patent term extension is the date on which the product received permission under the provision of law under which the applicable regulatory review period occurred. Even though the responsibility for regulatory review of certain food additives may involve both FDA and EPA, as pointed out by Applicant at page 4 of their request for reconsideration, the amount of extended term under § 156 for a food additive is based solely on regulatory review before the FDA. See 35 U.S.C. § 156(g)(2)(B).

3. No Objections Or Withdrawal Of Permission For Commercial Marketing Altered The End Of The Regulatory Review Period

Furthermore, Applicant argues that the statutory language of Section 156(g)(2)(B)(ii) indicates that the regulatory review period ends on the date that the food additive product can be commercially marketed, which in the case of Dantobrom®RW/Dantochlor®RW would have been after EPA approved the product under FIFRA. The USPTO does not agree with this argument. There are two circumstances in Section 156(g)(2)(B)(ii) indicating that the end of the regulatory review period is a date different than the issuance of a regulation. First, the statutory language indicates a change in the end date of the regulatory review period, "if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted." In the present regulatory review of Dantobrom®RW/Dantochlor®RW, no objections were filed with respect to the Federal Register publication of the amendment to the food additive regulations, so the end of the regulatory review period was not extended based on this statutory provision. Second, the statute indicates another possible change in the end date of the regulatory review period, "if commercial marketing was permitted and later revoked pending further proceedings as a result if such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted." In the present regulatory review of Dantobrom®RW/Dantochlor®RW, no objections were filed and commercial marketing was never revoked by FDA, as such the end of the regulatory review period was on the date of the Federal Register publication which amended the food additive regulations to include Dantobrom®RW/Dantochlor®RW. This is particularly relevant since the Federal Register publication triggers the sixty day period set forth in 35 U.S.C. § 156(d)(1). Because no objections or withdrawal of permission for commercial marketing altered the end of the regulatory review period of Dantobrom®RW/Dantochlor®RW, the date which triggered the sixty day window for submission of the PTE application is June 30, 2000. Therefore, the filing of the PTE application on August 30, 2000, was untimely and hence, the PTE application is **DENIED**.

B. Interim Extensions

1. Applicant's Pending Fifth Interim Extension Request Is Denied

Applicant filed for a fifth interim extension to extend the term of the '766 patent for another year because the '766 patent expired on February 9, 2007. Section 156(e)(2) of Title 35 provides for an interim patent term extension while an application's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. See Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '766 patent will not expire before a certificate of extension is issued or denied since the Director has denied Applicants' PTE application under 35 U.S.C. § 156(d)(1) as explained herein. The second requirement is not met because the Director issued a negative eligibility determination, thus divesting him of authority to grant an interim extension. See Somerset, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); see also In re Alcon Labs. Inc., 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for extension). Accordingly, because Applicant's PTE is denied herein and because the '766 patent is not eligible for patent term extension, the Office must deny Applicant's pending fourth interim extension request.

2. The Previously Granted Interim Extensions of the '766 Patent Are Vacated

During the pendency of Applicant's PTE Application before the USPTO, the USPTO granted interim extensions under 35 U.S.C. § 156(e)(2), extending the '766 patent for a total of four years while the USPTO determined whether the '766 patent was eligible for patent term extension. Because the USPTO has concluded herein that the '766 patent is not eligible for a patent term extension, the interim extensions previously granted under section 156(e)(2) are vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent

is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2).").

C. Conclusion

For the above-stated reasons, the applications for patent term extension under 35 U.S.C. § 156(d)(1) and § 156(e)(2) are **DENIED**. Applicant's request for reconsideration is **DENIED**; and the four interim extensions previously granted to Applicant under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*. This is a final agency decision.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755. E-mail inquiries should be directed to Mary.Till@uspto.gov.

Robert A. Clarke

Robert A. Clarke
Director
Office of Patent Legal Administration
Office of Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Dantobrom®RW/Dantochlor®RW
FDA Docket No.: 2001E-0096

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Nabeela R. McMillian
Marshall, Gerstein, & Borun, LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, IL 60606-6357

In re: Patent Term Extension
Application for
U.S. Patent No. 4,894,221

Dear Ms. McMillian:

This is in regard to the Renewed Requirement for Information of August 3, 2006, to which applicant responded on September 27, 2006.

Applicant is advised that the Power of Attorney is now accepted as in compliance with 37 CFR 3.73(b). The documents submitted with the response of September 27, 2006, together with documents previously submitted, establish a chain of title from the inventors to Sinclair Pharmaceuticals Limited, the present applicant for patent term extension.

In order to clarify the record, and to ensure that any Certificate of Extension that may eventually issue for this patent will reflect Sinclair Pharmaceuticals Limited as the owner, applicant is encouraged to file all relevant assignment and title documents, including those concerning change of corporate name, with the Assignment Division of the Office for recordation. Applicant should clearly indicate that the documents are being filed with regard to the '221 patent. It is noted that the assignment document submitted as Exhibit B with the response of September 27, 2006, although already on file with the Office, is not retrievable using either the patent number or the application number of the '221 patent because it was submitted to the Office with regard to a parent application.

An Order granting an interim extension of one year under 35 U.S.C. §156(e)(2) accompanies this letter. You will note that the Order was signed by Director Dudas on January 16, 2007.

Applicant is advised that the Office is currently awaiting confirmation by the Food and Drug Administration that DECAPINOL® Oral Rinse was subject to a regulatory review period within the meaning of 35 U.S.C. §156(g).

Any correspondence with respect to this matter should be directed as follows (NOTE NEW MAIL STOP):

Mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FAX: (571) 273-7754

Hand-carry: Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly J. Friedman

re: DECAPINOL® Oral Rinse

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sinclair Pharmaceuticals Limited	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,894,221	:	INTERIM EXTENSION

Sinclair Pharmaceuticals Limited, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,894,221, filed an application for patent term extension under 35 U.S.C. § 156 on June 17, 2005. The original term of the patent is due to expire on January 16, 2007. The patent claims a method of using 3-(4-propyl-heptyl)-4-(2-hydroxyethyl)morpholine (delmopinol), which is the active ingredient of the product DECAPINOL® oral rinse. That product was approved by the Food and Drug Administration for commercial marketing or use on April 18, 2005. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,894,221 is granted for a period of one year from the original expiration date of the patent.

1/16/07
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JAN 16 2008

Nabeela R. McMillian
Howrey LLP
C/O IP Docketing Dept.
2941 Fairview Park Dr., Suite 200
Falls Church, VA 22042-2924

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,894,221

Dear Ms. McMillian :

An order granting interim extension certificate under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,894,221 for a period of 1 year.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Decapinol® Oral Rinse
FDA Docket No.: 2006E-0366

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sinclair Pharmaceuticals Limited	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,894,221	:	INTERIM EXTENSION

Sinclair Pharmaceuticals Limited, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,894,221, filed an application for patent term extension under 35 U.S.C. § 156 on June 17, 2005. The extended term of the patent is due to expire on January 16, 2008. The patent claims a method of using 3-(4-propyl-heptyl)-4-(2-hydroxyethyl)morpholine (delmopinol), which is the active ingredient of the product DECAPINOL® oral rinse. That product was approved by the Food and Drug Administration for commercial marketing or use on April 18, 2005. An extension of five years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,894,221 is granted for a period of one year from the extended expiration date of the patent.

1/14/08
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOP PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Paper No. 31

ATTN: MAX D. HENSLEY
GENENTECH, INC.
460 POINT SAN BRUNO BLVD.
SOUTH SAN FRANCISCO, CA 94080

COPY MAILED

FEB 26 2002

OFFICE OF PETITIONS

ON PETITION

In re Patent No. 4,816,567 :
Issue Date: March 28, 1989 :
Application No. 06/483,457 :
Filed: April 8, 1983 :
Attorney Docket No. DT-2477 :

This is a decision on the petition filed February 7, 2002, to waive the rules and accept the correction of the assignee on the front page of the above-identified patent.

The petition is **granted.**

There is no indication that the person signing the present petition was ever given a power of attorney or authorization of agent to prosecute the above-identified patent. If the person signing the present petition desires to receive future correspondence regarding this patent, the appropriate power of attorney or authorization of agent must be submitted. While a courtesy copy of this decision is being mailed to the person signing the present petition, all future correspondence will be directed to the address currently of record until such time as appropriate instructions are received to the contrary.

This file is being forwarded to the Certificates of Correction Branch for issuance of the requested Certificate of Correction.

Telephone inquiries concerning this matter may be directed to the Certificates of Correction Branch at (703) 305-8309.

Christina T. Tartera

Christina T. Tartera
Petitions Attorney
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy
(703) 306-5589

cc: Sharon E. Crane
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON, TX 77056

COPY MAILED

OCT 3 1 2008

OFFICE OF PETITIONS

In re Patent No. 4,565,490	:	
Issue Date: January 21, 1986	:	
Application No. 06/486,336	:	DECISION ON PETITION
Filed: April 19, 1983	:	
Attorney Docket No.	:	

This is a decision on the petition under 37 CFR 1.182, filed September 4, 2008, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The petition is **GRANTED**.

The Office of Data Management is directed to issue a duplicate Letters Patent.

As authorized, the $400 fee for the petition under 37 CFR 1.182 has been assessed to petitioner's deposit account.

Telephone inquiries concerning this decision may be directed to JoAnne Burke at (571) 272-4584. Inquiries regarding the issuance of a duplicate Letters Patent may be directed to Naomi Farmer in the Office of Data Management at (703) 308-9250, Ext. 129.

A copy of this decision is being faxed to Office of Data Management for issuance of a duplicate Letters Patent.

Ramesh Krishnamurthy
Petitions Examiner
Office of Petitions

cc: Naomi Farmer, South Tower, 8th Floor, Room C23 (Fax No. (571) 270-9753)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: September 4, 2008 Signature: /Jason C. Huang, Reg. No. 46,222/
(Jason C. Huang)

PATENT
RICE/0003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ivan G. Rice	§	Confirmation No.: 1570
	§	
	§	Group Art Unit: 3403
Serial No.: 06/486,336	§	
	§	Examiner: Louis J. Casaregola
Filed: April 19, 1983	§	
	§	
For: INTEGRATED GAS/STEAM NOZZLE	§	

PETITION FOR REPLACEMENT LETTERS PATENT UNDER 37 C.F.R. § 1.182

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Jason C. Huang, attorney for the patent holder Ivan G. Rice, respectfully request a replacement Letters Patent Grant for U.S. Patent No. 4,565,490, issued on January 21, 1986. The reason for this request is that the original Letters Patent Grant was irreparably damaged during discovery in a litigation matter.

The fee for this petition in the amount of $400.00, as set forth under 37 C.F.R. § 1.17(f) (fee code 1462), has been submitted with the filing of this petition.

Prior to the filing of this Petition, Ivan G. Rice has filed a completed Power of Attorney and Correspondence Address Indication Form. Pursuant to that Form, please address all correspondence relating to this Petition—including the replacement Letters Patent Grant in the event this Petition is granted—to the following address:

Jason C. Huang
Patterson & Sheridan, LLP
3040 Post Oak Blvd.,
Suite 1500
Houston, TX 77056

Your assistance in this matter is greatly appreciated.

Respectfully submitted, and
S-signed pursuant to 37 C.F.R. 1.4,

/Jason C. Huang, Reg. No. 46,222/
Jason C. Huang, Reg. No. 46,222
PATTERSON & SHERIDAN, LLP
3040 Post Oak Blvd. Suite 1500
Houston, Texas 77056
Telephone: (713) 623-4844
Facsimile: (713) 623-4846

06/486336 Examiner: CASAREGOLA, LOUIS GAU: 3403
Inventor: RICE , IVAN Classification: 415/114.000
Status: 150 - PATENTED CASE
Title: INTEGRATED GAS/STEAM NOZZLE
Start Date: End Date:

bib_fee report (1 items, not sorted)

Acct Date	Seq. Num.	Tran Type	Fee Code	Fee Amount	Mailroom Date	Payment Method
09/04/2008	13077	4	1462	$400.00	09/04/2008	CC

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

MAY 19 2003

#20

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

A certificate under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Health Assessment Policy Staff
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	:	**CERTIFICATE OF** **INTERIM EXTENSION**

On March 5, 2003, patent owner Roche Palo Alto LLC timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine in the product RANEXA™. The application indicates that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (May 18, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for a period of one year from the original expiration date of the patent, i.e., from May 18, 2003, until May 18, 2004.

MAY - 9 2003

Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 22 2004

#22

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Isacson:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)
FDA Docket No:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	:	**CERTIFICATE OF INTERIM EXTENSION**

On March 29, 2004, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2004), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2005.

9/17/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN-02 2005

JUN - 2 2005

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

A certificate of interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. A notice regarding this interim extension will publish in the Federal Register on June 6, 2005. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC Request for Patent Term Extension U.S. Patent No. 4,567,264	: : :	**CERTIFICATE OF INTERIM EXTENSION**

On March 25, 2005, patent owner Roche Palo Alto LLC timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine in the product RANEXA™. The application indicates that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2005), a third interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the original expiration date of the patent, i.e., from May 18, 2005, until May 18, 2006.

5/26/05

Date

Jon W. Dudas

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE **[3510-16]**

[Docket No. 2005-P-064]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,567,264; ranolazine

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a third one-year interim extension of the term of U.S. Patent No. 4,567,264.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (571)272-7744; by mail marked to her attention and addressed to Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571)273-7744; or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On March 25, 2005, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional period of one year as required by 35 U.S.C. § 156(d)(5)(C). Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2005), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2006.

5/26/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 18 2006

Grant d. Green
Patent Law Department A2-250
Roche Palo Alto LLC
3401 Hillview Avenue
Palo Alto, CA 94304

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Green:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: RANEXA™ (ranolazine)

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,567,264	:	INTERIM EXTENSION

Roche Palo Alto LLC, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,567,264, filed a fourth application for interim patent term extension under 35 U.S.C. § 156(e)(2) on March 14, 2006. The previously extended term of the patent is due to expire on May 18, 2006. The patent claims the active ingredient ranolazine, in the human drug product RANEXA™, which was approved by the Food and Drug Administration for commercial marketing or use on January 27, 2006. An interim extension of one year is requested. U.S. Patent No. 4,567,264 was previously extended three times for a period of one year each under 35 U.S.C. 156(d)(5).

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,567,264 is granted for a period of one year from the extended expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 22 2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,567,264

Dear Mr. Isacson:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,567,264 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: RANEXA™ (ranolazine)
FDA Docket No:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Roche Palo Alto LLC	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,567,264	:	**INTERIM EXTENSION**

On March 29, 2004, patent owner Roche Palo Alto LLC, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,567,264. The patent claims the active ingredient ranolazine (Ranexa™). The application indicates, and the Food and Drug Administration (FDA) has confirmed, that a New Drug Application for the human drug product ranolazine has been filed and is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (May 18, 2004), the term of the patent will be extended under 35 U.S.C. § 156(d)(5) for an additional year.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,567,264 is granted for an additional period of one year from the extended expiration date of the patent, i.e., until May 18, 2005.

9/17/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

JUN 23 2003

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

JUN 23 2005

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.
Request for Patent Term Extension
U.S. Patent No. 4,585,597

CERTIFICATE OF INTERIM EXTENSION

On May 30, 2003, patent owner L'Oreal S.A. timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient (Mexoryl® SX (ecamsule)) in the product ANTHÉLIOS® SP Topical Cream (HELIOBLOCK® SX Cream), and the methods of use and manufacturing of the active ingredient. The application indicates that a New Drug Application for the human drug product ecamsule has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (June 16, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the original expiration date of the patent, i.e., from June 16, 2003, until June 16, 2004.

JUN 13 2003
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

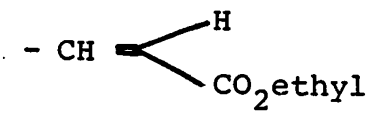
PATENT NO. : 4,585,597

DATED : April 29, 1986

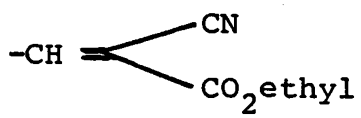
INVENTOR(S) : Gerard LANG et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, Example 5, that portion of the formula reading



should read



Signed and Sealed this

Twenty-second Day of December, 1987

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks

Staple Here Only !

PRINTER'S TRIM LINE

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

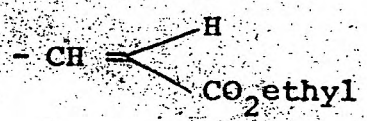
PATENT NO. : 4,585,597

DATED : April 29, 1986

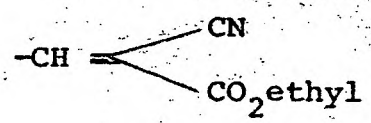
INVENTOR(S) : Gerard LANG et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, Example 5, that portion of the formula reading



should read



MAILING ADDRESS OF SENDER:
Fleit, Jacobson, Cohn & Price
1217 E Street NW
Washington, DC 20004-1998

PATENT NO. 4,585,597

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W241

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DATE: 05/23/03
PAGE: 00035

ACCESSION NUMBER 241-97-0330 BOX NUMBER 000099 LOCATION 09-60-35-2-1

FOLDER TITLE 4585597

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OLIPHANT BENNIE
U.S. PATENT & TRADEMARK OFFICE
FRANCONIA WAREHOUSE BUILDING 8A
6808 LOISDALE ROAD
SPRINGFIELD VA 22150
703-308-7400

SIGNATURE

DATE

00046395

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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL - 6 2004

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,597	:	**INTERIM EXTENSION**

On April 30, 2004, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl™ SX (ecamsule) in the human drug product ANTHÉLIOS™ SP, a method of use of ecamsule, and a method of manufacturing ecamsule. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product ANTHÉLIOS™ SP (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The patent was previously extended for a term of one year.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2004), an interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2005.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.go

JUN 23 2003

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597.

Dear Mr. Stepno:

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MEXORYL®
FDA Docket No.:

Additional enclosure: Courtesy copy of application for interim extension
No action required at this time.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.
Request for Patent Term Extension
U.S. Patent No. 4,585,597

CERTIFICATE OF INTERIM EXTENSION

On May 30, 2003, patent owner L'Oreal S.A. timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient (Mexoryl® SX (ecamsule)) in the product ANTHÉLIOS® SP Topical Cream (HELIOBLOCK® SX Cream), and the methods of use and manufacturing of the active ingredient. The application indicates that a New Drug Application for the human drug product ecamsule has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (June 16, 2003), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the original expiration date of the patent, i.e., from June 16, 2003, until June 16, 2004.

JUN 13 2003
Date

JAMES E. ROGAN
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 31 2006

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A. Request for Patent Term Extension U.S. Patent No. 4,585,597	:	**CERTIFICATE OF INTERIM EXTENSION**

On May 17, 2005, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product ANTHÉLIOS® SP, a method of use of the active ingredient, and a method of manufacturing the active ingredient. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mexoryl® SX (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2005), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for an additional year, i.e., until June 16, 2006.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2006.

3/29/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN 13 2006

Norman Stepno
Buchanan Ingersoll, PC
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,585,597 for a period of one year.

Telephone inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,597	:	**INTERIM EXTENSION**

On May 16, 2006, patent owner, L'Oreal S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,585,597. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product ANTHÉLIOS® SP (HELIOBLOCK® SX Cream), a method of use of the active ingredient, and a method of manufacturing the active ingredient. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mexoryl® SX (ecamsule) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (June 16, 2006), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for an additional year, i.e., until June 16, 2007.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,597 is granted for a period of one year from the extended expiration date of the patent, i.e., until June 16, 2007.

6/12/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

SEP 27 2006

Norman Stepno
Buchanan Ingersoll, PC
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,597

Dear Mr. Stepno :

A certificate of interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,585,597 up to June 10, 2007, or 1,455 days from the original expiration date of the patent.

Telephone inquiries regarding this communication should be directed to hte undersigned by telephone at (571) 272-7755, or at Mary.Till@uspto.gov by e-mail.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: ANTHÉLIOS® SP Topical Cream (Mexoryl® SX (Ecamsule))
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re L'Oreal S.A. Request for Patent Term Extension U.S. Patent No. 4,585,597	: : :	**CERTIFICATE OF INTERIM EXTENSION**

L'Oreal S.A., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,585,597, filed an application for patent term extension under 35 U.S.C. § 156 on September 19, 2006. Three interim extensions have been granted for the patent under 35 U.S.C. § 156(d)(5), each for a period of one year. The extended term of the patent is due to expire on September 19, 2006. The patent claims the active ingredient Mexoryl® SX (ecamsule) in the human drug product, ANTHÉLIOS® SX Daily Moisturizing Cream with Sunscreen, a method of use of the active ingredient, and a method of manufacturing the active ingredient, which was approved by the Food and Drug Administration for commercial marketing or use on July 21, 2006. An extension of 1,455 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,585,597 is granted for a period of 1,455 days from the original expiration date of the patent, i.e., until June 10, 2007.

9/19/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED

SEP 22 2009

OFFICE OF PETITIONS

VENABLE LLP
P.O. BOX 34385
WASHINGTON DC 20043-9998

In re Application of
Albert Dunn et al
Application No. 06/531,939
Filed: September 7, 1983
Attorney Docket No. SB-186

ON PETITION

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed August 11, 2009, to revive the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.137(b)." This is **not** a final agency action within the meaning of 5 U.S.C. § 704.

The application became abandoned for failure to reply in a timely manner to the Office letter mailed December 15, 2006.

A grantable petition under 37 CFR 1.137(b) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d). Where there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137 was unintentional, the Director may require additional information. See MPEP 711.03(c)(II)(C) and (D). The instant petition lacks item(s) (4).

The Office is in receipt of a Terminal Disclaimer submitted on August 11, 2009. However, the Terminal Disclaimer form is incomplete because no owner was provided. A proper Terminal Disclaimer is required.

Further correspondence with respect to this matter should be delivered through one of the following mediums:

By mail:	Mail Stop PETITIONS Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450
By hand:	Customer Service Window Mail Stop Petitions Randolph Building 401 Dulany Street Alexandria, VA 22314
By fax:	(571) 273-8300 ATTN: Office of Petitions
By internet:	EFS-Web www.uspto.gov/ebc/efs_help.html (for help using EFS-Web call the Patent Electronic Business Center at (866) 217-9197)

Any questions concerning this matter may be directed to the undersigned at (571) 272-3208.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

VENABLE LLP
P.O. BOX 34385
WASHINGTON DC 20043-9998

MAILED

NOV 25 2009

OFFICE OF PETITIONS

In re Application of :
Albert Dunn et al :
Application No. 06/531,939 : DECISION ON PETITION
Filed: September 7, 1983 :
Attorney Docket No. SB-186 :

This is a decision on the renewed petition under the unintentional provisions of 37 CFR 1.137(b), filed October 7, 2009, to revive the above-identified application.

The petition is **GRANTED**.

The petition satisfies the conditions for revival pursuant to the provisions of 37 CFR 1.137(b) in that (1) the reply, (2) the petition fee; and (3) the required statement of unintentional delay have been received. Accordingly, the reply to the Office letter mailed December 15, 2006, is accepted as having been unintentionally delayed.

The $140.00 fee for the Terminal Disclaimer submitted on October 7, 2009 is being credited to petitioner's deposit account no. 22-0261, since the fee was previously paid with the Terminal Disclaimer submitted on August 11, 2009.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3208.

This application is being referred to Technology Center AU 3662 for appropriate action by the Examiner in the normal course of business on the reply received October 7, 2009 and on August 11, 2009.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 31 2006

David Gryte
Intervet Inc.
29160 Intervet Lane
Millsboro, DE 19966

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,585,770

Dear Mr. Gryte:

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,585,770 three times for a period of one year each, initially from October 12, 2003, to October 12, 2004, from October 12, 2004 to October 12, 2005, and from October 12, 2005, to October 12, 2006.

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Kery A Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE:
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In Hoechst Roussel Vet S.A.	:	
Request for Patent Term Extension	:	**CERTIFICATE OF**
U.S. Patent No. 4,585,770	:	**INTERIM EXTENSION**

On March 26, 2003, patent owner, Hoechst Roussel Vet S.A., timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,585,770. On March 31, 2004, patent owner, Hoechst Roussel Vet S.A., timely filed a second application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,585,770. On March 29, 2005, patent owner, Hoechst Roussel Vet S.A., timely filed a third application under 35 U.S.C. § 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,585,770. The patent claims the active ingredient, zilpaterol hydrochloride, in the animal drug product Zilmax®. The application indicates that an Investigational New Animal Drug Application for the animal drug product, Zilmax® (zilpaterol hydrochloride), has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (October 12, 2003), the term of the patent is extended under 35 U.S.C. § 156(d)(5) for a period of one year to October 12, 2004, for an additional year to October 12, 2005, and for another additional year, i.e., until October 12, 2006.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for a period of one year from the original expiration date of the patent, i.e., until October 12, 2004; a second interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for an additional period of one year from the extended expiration date of the patent, i.e., until October 12, 2005; and a third interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,585,770, is granted for an additional period of one year from the extended expiration date of the patent, i.e., until October 12, 2006.

3/29/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 18 2006

Roger L. Browdy
Browdy and Neimark PLLC
624 Ninth Street NW
Suite 300
Washington DC 20001-5303

In Re: Patent Term Extension Application
for U.S. Patent No. 4,840,896

Dear Mr. Browdy:

An ORDER GRANTING INTERIM EXTENSION under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,840,896 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda by telephone at (571) 272-7754, or by e-mail at kathleen.fonda@uspto.gov.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: OVIDREL®
FDA Docket No.: 2005E-0256

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Genzyme Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,840,896	:	INTERIM EXTENSION

Genzyme Corporation, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,840,896, filed an application for patent term extension under 35 U.S.C. § 156 on November 20, 2000. The original term of the patent is due to expire on June 20, 2006. The patent claims the active ingredient choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)), in the human drug product OVIDREL®, which was approved by the Food and Drug Administration for commercial marketing or use on September 20, 2000. An extension of 1,054 days was originally requested, but applicant's Request for Interim Extension Under 35 U.S.C. § 156(e)(2) of March 13, 2006, now requests an extension until April 28, 2009, (1,043 days) in view of the corrected regulatory period set forth in the Food and Drug Administration's (FDA) letter of February 24, 2006.

The initial USPTO review of the application to date indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. On March 15, 2006 (71 Fed. Reg. 50), the FDA published the determination of the regulatory review period for purposes of patent term extension for OVIDREL®, but this determination has not yet been made final. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,840,896 is granted for a period of one year from the original expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL - 6 2004

Basil Krikelis
RatnerPrestia, Nemours Building
1007 Orange Street, Suite 1100
P.O. BOX 1596
WILMINGTON, DE 19899

Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of one year.

It is noted that the application for interim patent term extension was accompanied by a change of address for the patent, and a revocation of power of attorney. The address was requested to be changed to the address associated with Customer Number 31344, which is a slightly different address than above. Applications for patent term extension do not use the address associated with a Customer Number, since neither the Food and Drug Administration nor the Department of Agriculture have direct access to that database, so if the address associated with the application for patent term extension needs to be changed, applicant should submit a change of address specific to the application for patent term extension.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences :
Request for Patent Term Extension : **CERTIFICATE OF**
U.S. Patent No. 4,600,706 : **INTERIM EXTENSION**

On November 3, 2003, patent owner Arkion Life Sciences timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,600,706. The patent claims the method of making the animal feed product NSURE® (natamycin). The application indicates that an amended Food Additive Petition for the animal feed product has been filed and was undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The petition was granted by the Food and Drug Administration, and the regulations for food additives in feed and drinking water were amended to provide for the safe use of natamycin. See Food Additives Permitted in Feed and Drinking Water of Animals; Natamycin, 69 Fed. Reg. 19320 (April 13, 2004) (final rule).

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since regulatory review period continued beyond the expiration date of the patent (November 17, 2003, due to the terminal disclaimer disclaiming the term of the patent subsequent to the expiration date of U.S. Patent No. 4,536,494), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the expiration date of the patent, i.e., until November 17, 2004.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE [3510-16]

[Docket No. 2004-P-040]

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,600,706; natamycin

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,600,706.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (703)306-3159; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Patent Ext., P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (703)872-9411, or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On November 3, 2003, patent owner Arkion Life Sciences timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,600,706. The patent claims the method of making the animal feed product NSURE® (natamycin). The application indicates that an amended Food Additive Petition for the animal feed product has been filed and was undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The petition was granted by the Food and Drug Administration, and the regulations for food additives in feed and drinking water were amended to provide for the safe use of natamycin. See Food Additives Permitted in Feed and Drinking Water of Animals; Natamycin, 69 Fed. Reg. 19320 (April 13, 2004) (final rule).

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since regulatory review period continued beyond the expiration date of the patent (November 17, 2003, due to the terminal disclaimer disclaiming the term of the patent subsequent to the expiration date of U.S. Patent No. 4,536,494), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the expiration date of the patent, i.e., until November 17, 2004.

6/24/04
Date

Jon W. Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOV 17 2004

Basil Krikelis
RatnerPrestia, Nemours Building
1007 Orange Street, Suite 1100
P.O. BOX 1596
WILMINGTON, DE 19899

Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

A certificate of interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (571)272-7744.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Interim Extension

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003 until November 17, 2004. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 348) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2005.

11/04/04
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003 until November 17, 2004, and for a second year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2004 until November 17, 2005. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2006.

10/18/05
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 30 2006

Basil Krikelis
McCarter & English
919 N. Market Street
PO Box 111
Wilmington DE 19801-3023

OE BAL 11-9-06

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

Dear Mr. Krikelis :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NSURE®
FDA Docket No.: 2005E-0250

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences :
Request for Patent Term Extension : **ORDER GRANTING**
U.S. Patent No. 4,600,706 : **INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003, until November 17, 2004, and for a second year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2004, until November 17, 2005, and for a third year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2005, until November 17, 2006. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2007.

10/20/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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OCT 30 2006

Basil Krikelis
McCarter & English
919 N. Market Street
PO Box 111
Wilmington DE 19801-3023

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

Dear Mr. Krikelis :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,600,706 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: NSURE®
FDA Docket No.: 2005E-0250

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Arkion Life Sciences	:	
Request for Patent Term Extension	:	**ORDER GRANTING**
U.S. Patent No. 4,600,706	:	**INTERIM EXTENSION**

On May 13, 2004, Arkion Life Sciences, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,600,706, filed an application under 35 U.S.C. § 156, requesting an extension of five years. The patent was previously extended for a period of one year pursuant to 35 U.S.C. 156(d)(5), from November 17, 2003, until November 17, 2004, and for a second year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2004, until November 17, 2005, and for a third year pursuant to 35 U.S.C. 156(e)(2), from November 17, 2005, until November 17, 2006. The patent claims a method of use of natamycin, an additive contained in the animal feed product "NSURE®." The application indicates that the product has undergone a regulatory review under Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because it is apparent that processing of the application for patent term extension will not be completed before the extended expiration date of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,600,706 is granted for a period of one year from the extended expiration date of the patent, until November 17, 2007.

10/20/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
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NOV 13 2007

Basil Krikelis
McCarter & English
Citizens Bank Center
919 N. Market Street, Suite 1800
P.O. Box 111
Wilmington, DE 19899

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156

This is in response to the application for extension of the patent term of U.S. Patent No. 4,600,706 (the '706 patent) filed under 35 U.S.C. § 156 in the United States Patent and Trademark Office (USPTO) on May 13, 2004, the request for reconsideration filed March 7, 2007, and the request for an interim extension of the '706 patent filed under 35 U.S.C. § 156(e)(2) on October 22, 2007. The application was filed by Arkion Life Sciences, Inc. (Applicant), the patent owner of record at the time application was filed. Extension was sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a food additive known by the tradename NSURE® which comprises natamycin. Because the Food and Drug Administration (FDA) and the PTO have determined that the approval of NSURE® (natamycin) does not constitute the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred, Applicant's requests for extension of the patent term of the '706 patent under 35 U.S.C. § 156(d)(1) and 35 U.S.C. § 156(e)(2) are **DENIED** and its request for reconsideration is **DENIED**. Additionally, the three interim extensions previously granted under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

A. Factual Background

In February of 1998, the FDA announced that Protein Technologies International filed a petition to amend the food additive regulations to provide for the safe use of a dry form of natamycin (pimaricin) as an antimycotic in food to inhibit mold spoilage. See Protein Technologies International; Filing of Food Additive Petition, 63 Fed. Reg. 6945 (Feb. 11, 1998). The FDA indicated that approval of a food additive occurs under section 409(b)(5) of the FFDCA (21 U.S.C. § 348(b)(5)). Id.

In December of 1998, the FDA amended the food additive regulation, 21 C.F.R. § 172.155, to provide for the safe use of a dry form of natamycin as an antimycotic on the surface of cuts and slices of cheese. See Food Additives Permitted for Direct Addition to Food for Human Consumption; Natamycin (Pimaricin), 63 Fed. Reg. 66014-15 (Dec. 1, 1998). Notably, the FDA acknowledged that natamycin was already used as an antimycotic agent for cheese when applied an aqueous solution by dipping or spraying. Id.

On April 13, 2004, the FDA approved the Food Additive Petition No. 2234 for NSURE® (natamycin) as an animal feed additive for use in broiler chicken feed to retard or inhibit the growth of *Aspergillus Parasiticus* fungi.

One month later, on May 13, 2004, Applicant filed an application to extend the term of the '706 patent (PTE Application) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO.[1] In its PTE Application, Applicant alleges that the '706 patent claims a method for using the product NSURE® (natamycin). Applicant likewise alleged that NSURE® (natamycin) "is currently subject to review under Section 409(b)(1) of the [FFDCA] (the act) (21 U.S.C. § 348(a))."

On November 17, 2004, the USPTO sent a letter to the FDA requesting assistance in determining the eligibility of the '706 patent for extension under 35 U.S.C. § 156(d)(1) based on the premarket review of NSURE® (natamycin). The USPTO indicated that it initially determined that the '706 patent was eligible for extension.

In a letter dated July 24, 2006, the FDA indicated that NSURE® (natamycin) had been subject to regulatory review period under section 409 of the FFDCA before its commercial marketing or use, but that the approval did not represent the first permitted commercial marketing or use of the active ingredient of NSURE® (natamycin) under 21 U.S.C. § 348, the provision of law under which the regulatory review period occurred. The FDA stated: "NSURE does not represent the first permitted commercial marketing or use of the food additive natamycin under 21 U.S.C. § 348, the provisions of law under which the regulatory review period occurred."

On September 7, 2006, the USPTO mailed a notice of final determination to Applicant, dismissing the PTE Application on grounds that not all of the requirements of 35 U.S.C. § 156 were satisfied. Specifically, in light of the FDA's letter, the USPTO explained that NSURE® (natamycin) did not constitute the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred as required by 35 U.S.C. § 156(a)(5)(A).

On March 7, 2007, Applicant requested reconsideration of the dismissal, arguing that the provision of law under which the food additive petition for NSURE® (natamycin) was filed (i.e., 21 C.F.R. § 573) is a different provision of law than the provision of law that the FDA referenced

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[1] The '706 patent expired by operation of law on November 17, 2003. However, Applicant filed a series of interim extension requests, which the USPTO granted, extending the term of the '706 patent on an interim basis pending completion of both FDA regulatory review process and the PTE application review. Specifically, Applicant filed its first interim extension request under 35 U.S.C. § 156(d)(5) on November 3, 2003, extending the '706 patent for one-year until November 17, 2004. It then filed three other interim extension requests, all under 35 U.S.C. § 156(e)(2), each extending the patent by one more year such that the patent will expire on November 17, 2007.

in its letter (i.e., 21 U.S.C. § 348).

On October 22, 2007, Applicant filed a fourth interim extension request under 35 U.S.C. § 156(e)(2) for the '706 patent.

B. U.S. Patent No. 4,600,706 Is Not Eligible for Patent Term Extension

Under 35 U.S.C. § 156(a), the term of a patent which claims a product shall be extended if six specific requirements are satisfied. Subparagraph (a)(5)(A) provides in pertinent part that "the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A) (emphases added).

Here, Applicant's product, NSURE® (natamycin), fails to meet the requirement of 35 U.S.C. § 156(a)(5)(A) because NSURE® (natamycin) does not represent the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred (i.e., 21 U.S.C. § 348). Applicant states in its PTE Application at page 3 that its feed additive "was subject to review under Section 409(b)(1) of the [FFDCA] (the Act) (21 U.S.C. § 348(a))." The FDA also pointed to 21 U.S.C. § 348 as being the applicable "provision of law" for the regulatory review period of NSURE® (natamycin) in its response to the USPTO's request for input. The USPTO, however, uncovered that natamycin (pimaricin) had been previously approved as a food additive under Section 409 of the FFCDA (21 U.S.C. § 348) for use as an antimycotic agent in cheese sometime before 1998. See 63 Fed. Reg. 6945. As a result, NSURE® (natamycin) plainly is not the first permitted marketing or use of natamycin under 21 U.S.C. § 348.

In its request for reconsideration, Applicant argues that the '706 patent is entitled to an extension under 35 U.S.C. § 156 because NSURE® (natamycin) was approved under 21 C.F.R. § 573, which although obtaining authority from 21 U.S.C. § 348, is a different provision of law than 21 U.S.C. § 348. Applicant is mistaken in its reading of 35 U.S.C. § 156(a)(5)(A). The phrase "provision of law" as used in 35 U.S.C. § 156(a)(5)(A) refers to the statutory provision under which the regulatory review period occurs for a particular class of products that is eligible for patent term restoration. It does not refer to a particular provision of a regulation, as argued by Applicant.

Section 156(g) of Title 35 and its implementing regulations confirm the USPTO's reading of 35 U.S.C. § 156(a)(5)(A). That is, 35 U.S.C. § 156(g) and its implementing regulations identify the statutory authorities under which regulatory review occurs for food and color additives.[2]

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[2] Notably, for all other classes of products for which patent term restoration is available, § 156(g) reflects statutory provisions under which regulatory review occurs: (i) section 505 of the FFDCA for new drugs; (ii) section 505 of the FFDCA and section 351 of the Public Health Service Act for licensed biologics; (iii) section 515 of the FFDCA for medical devices;

35 U.S.C. § 156(g) refers in general to the FFDCA for food additives and not to a regulation such as 21 C.F.R. § 573. The implementing regulations for 35 U.S.C. § 156(g), in turn, are more specific and refer to section 409 of the FFDCA. See 21 C.F.R. § 60.3(b)(9) (indicating that the provision of law for food additives is section 409 of the FFDCA).

For the foregoing reasons, the term of the '706 patent is not eligible for extension under 35 U.S.C. § 156 based upon the regulatory review period and approval of the product NSURE® (natamycin) as a feed additive.

C. Applicant's Pending Fourth Interim Extension Request Is Denied

Applicant filed a fourth interim extension application to extend the term of the '706 patent for another year because the '706 patent is due to expire on November 17, 2007. Section 156(e)(2) of Title 35 provides for an interim patent term extension while an applicant's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. See Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '706 patent will not expire before a certificate of extension is issued or denied since the Director has denied Applicants' PTE application under 35 U.S.C. § 156(d)(1) herein as explained above. The second requirement is not met because the Director issued a negative eligibility determination, thus divesting him of authority to grant an interim extension. See Somerset, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); see also In re Alcon Labs. Inc., 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for

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and (iv) section 512 of the FFDCA for new animal drugs. Section 156(g) never mentions any regulations.

extension). Accordingly, because Applicant's PTE is denied herein and because the '706 patent is not eligible for patent term extension, the Office must deny Applicant's pending fourth interim extension request.

D. The Previously Granted Interim Extensions of the '706 Patent Are Vacated

During the pendency of Applicant's PTE Application before the USPTO, Applicant filed three previous interim extension requests under 35 U.S.C. § 156(e)(2). The USPTO granted each of the requests, extending the '706 patent for a total of three years while the USPTO determined whether the '706 patent was eligible for patent term extension. Because the USPTO has concluded herein that the '706 patent is not eligible for a patent term extension, the interim extensions previously granted under section 156(e)(2) are vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2).").

E. Conclusion

In sum, Applicant's requests for extension of the patent term of the '706 patent are **DENIED**; Applicant's request for reconsideration is **DENIED**; and the three interim extensions previously granted to Applicant under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

THIS DECISION MAY BE VIEWED AS A FINAL AGENCY ACTION.

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Office of the Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy
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Attention: Beverly Friedman

Re: NSURE® (natamycin)
FDA Docket No. 2005E-0250